

## **REMARKS**

The Office Action mailed April 6, 2010 (hereinafter, “Office Action”) has been reviewed and the Examiner’s comments considered. Claims 1-11, 14-22, and 27-32 are pending in this application. Claims 28-32 are withdrawn from consideration, and are canceled without prejudice or disclaimer by this amendment. Claim 22 is amended to correct an inadvertent typographical error. Applicants submit that no new matter is introduced.

### **Claim Objections**

Claim 22 is objected to because of the informality of a typographical error. Claim 22 is amended herein to correct the spelling of “polytetrafluoroethylene.” Accordingly, Applicants respectfully request withdrawal of the objection.

### **Claim Rejections - 35 U.S.C. § 102**

Claims 1-5, 7-11, 14, 16, 18, 19, and 21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by USPN 5,156,619 to Ehrenfeld (“Ehrenfeld”). Applicants respectfully traverse this rejection.

The Office Action alleges that Ehrenfeld discusses a “generally uniform surface” and a first nominal or minimal inner diameter “that tapers to a smaller second nominal or minimal inner diameter” adjacent the end formation. The support for these assertions is purportedly found in columns 1 and 2 of Ehrenfeld. However, respectfully, Applicants submit that Ehrenfeld does not show or describe the features alleged to be disclosed.

First, with respect to the purported disclosure of a generally uniform surface, the cited Ehrenfeld passage (col. 1:65 to col. 2:5) describes reinforcing a bifurcated graft through stitches to close space between legs formed during knitting or weaving, and also the presence of circular crimps about the body and legs of the graft. Nowhere is a generally uniform surface shown or described by Ehrenfeld. Indeed, the presence of crimps *necessarily* means that any tubular portion shown does not include a “generally uniform surface,” as recited in independent claim 1, or a “first

diameter portion extending along a majority of the length of the tube” as recited in independent claims 18 and 21.

Second, with respect to the purported disclosure of a first diameter that tapers to a smaller second diameter adjacent the end formation, the cited Ehrenfeld support (col. 1:51-57, col. 2:17-20, col. 2:6-9, FIGS. 1-3) shows and describes the prior art cutting of a graft from a bifurcation and reinforcing the harvested graft with stitches. Nowhere in the Ehrenfeld specification or drawings is there disclosed a tubular portion having “a first diameter that tapers to a smaller second diameter adjacent an end formation,” as recited in independent claim 1, and similarly recited in independent claims 18 and 21. Applicants submit that the crimps formed in the shown grafts cannot fairly be interpreted as a tubular portion including a generally uniform surface that tapers from a first diameter to a smaller second diameter.

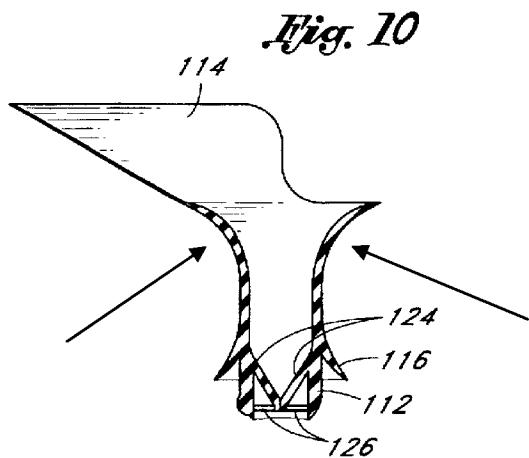
Accordingly, Applicants respectfully submit that Ehrenfeld does not anticipate independent claims 1, 18, and 21, because not all of the claimed features are shown or described thereby. Therefore, independent claims 1, 18, and 21, and claims 2-5, 7-11, 14, 16, and 19, depending therefrom, are patentable over Ehrenfeld, and Applicants request favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 102.

Claims 1-5, 7, 14, 16, 18, 19, 21, and 27 stand rejected under 35 U.S.C. § 102(e) as being anticipated by USPN 5,782,916 to Pintauro et al. (“Pintauro”). Applicants respectfully traverse this rejection.

The Office Action alleges that Pintauro FIG. 13 illustrates an end formation 114 capable of connection to a blood vessel opening, citing passages in Pintauro that discuss the first anchor 114. The Office Action also alleges that Pintauro describes a first diameter portion tapering to a smaller second diameter portion, citing to a passage that describes a *proximal* portion of the tubular body 112 that kinks or collapses. However, respectfully, Applicants submit that Pintauro does not show or describe the features alleged to be disclosed.

Pintauro is directed to a device for maintaining urinary continence, the device inserted in a *nonsurgical* procedure using a cystoscope. (Pintauro, col. 9:8-14.) With respect to the allegation that Pintauro illustrates an end formation capable of connection to a blood vessel opening, Applicants respectfully disagree. The Pintauro device, as clearly shown in FIGS. 1 and 8, has an anchor 114 that extends only *partially* around the end 18, 118 of the tubular body 12, 112. At least because of this configuration, the Pintauro device is not “configured for surgical connection to an opening formed in a blood vessel” as recited in independent claim 1. It is further noted that because Pintauro is designed for insertion into a bladder for purposes of regulating urination, it is formed from rubber and rubber-like materials. (Pintauro, col. 8:38-44.)

With respect to the allegation that Pintauro describes a first diameter portion tapering to a smaller second diameter portion adjacent the end formation, Applicants respectfully submit that Pintauro actually shows and describes precisely the *opposite* configuration, i.e., a first diameter portion tapering to a larger second diameter portion adjacent the end formation. This can clearly be seen in Pintauro FIG. 10 reproduced below, which is annotated with arrows to show the portion adjacent the end formation.



Accordingly, Pintauro does not show or describe “a first diameter that tapers to a smaller second diameter adjacent an end formation,” as recited in independent claim 1, and similarly recited in independent claims 18 and 21.

Applicants further submit that Pintauro does not show or describe “an enlarged chamber” as recited in independent claims 1, 18, and 21. Consistent with the specification as originally filed, the word “chamber” means an enclosed space or compartment. The anchor 14, 114 of Pintauro extends only partially around the circular end of the tubular body 12, and therefore does not form a chamber as required.

For the same reason, with respect to independent claim 27, the anchor 14, 114 of Pintauro does not show a second portion with a variable *inner* dimension, or a second portion defining a non-circular *opening*, or an opening defining a cross-sectional *area*. Specifically: 1) without a bounded region, there cannot be an inner dimension, 2) without a bounded region, an opening cannot be defined, and 3) without a bounded region (or an opening), a cross-sectional area cannot be defined (area being generally defined as a quantity expressing the two-dimensional size of a defined part of a surface, typically a region bounded by a closed curve).

Accordingly, Applicants respectfully submit that Pintauro does not anticipate independent claims 1, 18, 21, and 27, because not all of the claimed features are shown or described thereby. Therefore, independent claims 1, 18, 21, and 27, and claims 2-5, 7, 14, 16, and 19, depending therefrom, are patentable over Pintauro, and Applicants request favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 102.

### **Claim Rejections - 35 U.S.C. § 103**

Claims 6, 15, 17, 20, and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ehrenfeld. Applicants respectfully traverse this rejection. Without conceding the allegations in the Office Action, Applicants submit that claims 6, 15, 17, 20, and 22 depend from a patentable independent claim, in view of the above, and are therefore patentable for at least this reason. Accordingly, Applicants request favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

Claims 6, 15, 17, 20, and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Pintauro. Applicants respectfully traverse this rejection. Without conceding the allegations in

the Office Action, Applicants submit that claims 6, 15, 17, 20, and 22 depend from a patentable independent claim, in view of the above, and are therefore patentable for at least this reason. Accordingly, Applicants request favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

Claim 27 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over USPN 4,530,113 to Matterson (“Matterson”). Applicants respectfully traverse this rejection.

The Office Action alleges that forming the shunt 10 of FIG. 6 without the pleats or corrugations 12 would have been an “obvious step backward” in order to simplify manufacture. The Office Action further alleges that the inner arc lengths and diameters along the ends are “variable by virtue of the oblique cut.” (Office Action, p. 3.) Applicants respectfully disagree.

First, Matterson teaches to crimp the graft to provide circumferential pleats or corrugations “that help maintain the graft in its open tubular configuration even as it is bent during surgery to accommodate to anatomical requirements.” (Matterson, col. 6:50-54.) Thus, the alleged obvious step backward, instead of being beneficial as suggested, would render the Matterson graft inoperable for its intended purpose, according to Matterson, as the graft would be prone to closing or bending during surgery.

Second, even assuming *arguendo* that the “obvious step backward” did not render the Matterson graft inoperable for its intended purpose, there is no disclosure of a “second portion with a variable inner dimension along a second portion of the central axis,” as claimed. The oblique cuts of the Matterson graft do not change the inner dimension of the graft lumen, and therefore cannot confer to the graft a variable inner dimension along a second portion of the central axis. Thus, even assuming *arguendo* that the Matterson graft at the oblique cuts shows a second and third non-circular opening defining a cross-sectional area that is larger than a cross-sectional area of the first portion of the tube, Matterson does not show a second portion with a *variable inner dimension* along a second portion of the central axis, as claimed.

Accordingly, Applicants respectfully submit that Matterson does not establish a *prima facie* case of obviousness with respect to claim 27, and therefore request favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

### **Conclusion**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

It is noted that the remarks herein do not constitute, nor are they intended to be, an exhaustive enumeration of the distinctions between the cited references and the claimed invention. Rather, the distinctions identified and discussed herein are presented solely by way of example. Consistent with the foregoing, the discussion herein should not be construed to prejudice or foreclose future consideration by Applicants of additional or alternative distinctions between the claims of the present application and the references cited by the Examiner and/or the merits of additional or alternative arguments.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-2191, under Order No. 101675.0070P2 from which the undersigned is authorized to draw.

Dated: July 6, 2010

Respectfully submitted,

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